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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,324	06/20/2003	Ciaran N. Cronin	SYR-EPHA2-5001-C1	4969
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TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121				
EXAMINER NOAKES, SUZANNE MARIE				
ART UNIT		PAPER NUMBER		

1653

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/601,324

Applicant(s)

CRONIN ET AL.

Examiner

Suzanne M. Noakes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-6,9,10,12-15,17 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,9,10,12-15,17 and 26-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

1. Amendments to the claims, specification and drawings filed 10 July 2006 are acknowledged. Applicants have cancelled claims 18-25 and added new claims 26-33. Claims 1, 2, 4-6, 9-10, 12-15, 17 and 26-33 are pending and under examination.

### ***Withdrawal of Objections/Rejections***

2. The objection for non-compliance of the sequence rules, stated in section 8 of the previous Office action, is hereby withdrawn in view of the amendments to the Figures.

3. The objection to the Drawings recited in section 9 of the previous Office action is hereby withdrawn in view of the filing of replacement drawing sheets which rectify the objections of record.

4. The objections to the specification for lacking a non-descript title and inadequate abstract recited in sections 10 and 11 of the previous Office action are hereby withdrawn in view of the new title and amended abstract.

5. The objection to the claims for improper use of SEQ ID NO: identifier and use of acronyms with no accompanying description, recited in sections 12 and 13 of the previous Office action, are hereby withdrawn in view of the amendments to the claims and specification.

6. The rejection of claims 4 and 12 under 35 U.S.C. § 112 2<sup>nd</sup> paragraph recited in section 14 of the previous Office action is withdrawn in view Applicants

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bona fide attempt to clarify the claim limitation. However, see new Claim

Objections recited below.

7. The rejection of claims 7, 8 and 16 under 35 U.S.C. § 112 2<sup>nd</sup> paragraph is withdrawn and obviated by Applicants cancellation of said claims.

8. The rejection of claim 16 under 35 U.S.C. 102(b) is withdrawn and obviated by Applicants cancellation of the claim.

### ***Maintained Objections/Rejection***

#### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Written Description**

10. Claims 1, 2, 4-6, 9-10, 12-15, 17 (now added) and 26-33 (new claims, commensurate in scope with the rejected claims) are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The details of the rejection is recited in the previous Office action in Section 17.

#### **Scope of Enablement:**

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11. Claims 1, 2, 4-6, 9-10, 12-15, 17 (now added) and 26-33 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement. The details of the rejection are recited in Section 18 of the previous Office action.

### ***New Claim Objections/Rejections***

#### ***Claim Objections***

12. Claims 4 and 12 are objected to because of the following informalities:  
The terms for defining the limitation of resolution is still ambiguous. The examiner suggests reciting that a 'a higher resolution than 3 Å' as a way to avoid all ambiguity because those skilled in the art know the stark difference between 'high resolution' and 'low resolution' (see additional comments in the Response to Arguments). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Written Description and Enablement:**

14. Claim 17 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 is now included in the rejection for lacking

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written description for the same reasons of record as recited above in Section 9 of the instant Office and Section 17 of the previous Office action and is further elaborated upon below.

15. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising a protein consisting of SEQ ID No: 3, wherein the composition when drawn to crystals is limited to a crystal consisting SEQ ID No: 3, with the space group  $P3_221$  and unit cell parameters  $a=72.12$ ,  $b=72.12$  and  $c=241.62$  Å, does not reasonably provide enablement for all crystal forms consisting of SEQ ID No: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims when read in light of the specification, encompass crystal compositions comprising a polypeptide consisting of SEQ ID No: 3. Thus, the claims lacks scope of enablement for the same reasons that the crystal composition of claim 1 lacks scope of enablement and is recited above in the instant Office action is Section 10 which refers to the previous Office action, Section 18.

### ***Response to Arguments***

16. Applicant's arguments filed 10 July 2006 have been fully considered but they are not persuasive.

17. The examiner wishes to thank Applicants for their bona fide attempt to clarify the issues of resolution recited in claims 4 and 12. However, in an attempt

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to fully clarify the issue and recite the limitation which Applicants intend for these claims, the Examiner suggests reciting '.....wherein the protein crystal diffracts X-rays for a determination of structure coordinates to a higher resolution than 3 Å."

There is no ambiguity for those skilled in the art when dealing with "high resolution" and "low resolution". A skilled artisan clearly and immediately recognizes that high resolution means a lower number in angstroms, whereas low resolution means a number that is numerically larger; however, the quality of the two is drastically different wherein "higher resolution" is equal to higher quality. As stated, it is the Examiner's belief that this is what Applicants are intending to claim, a higher quality crystal that produces higher quality X-ray data which in turn produces a higher quality electron density map.

18. The examiner has maintained the rejection for lack of written description and enablement of claims 1, 2, 4-6, 9, 10, 12-15, and new claims 26-33; wherein claim 17 is now also rejected for the same reasons. Applicants assert that the amendment of independent claims 1 and 9 to precisely state that the crystalline composition consists of SEQ ID No: 3, that this is sufficient to overcome the rejections of record. However, the examiner respectfully disagrees that this is enough to provide scope of enablement and written description. Rather, what is needed is the inclusion of the space group and unit cell parameters to fully define Applicants invention and overcome the 35 U.S.C. 112 1<sup>st</sup> paragraph rejections because the art of protein crystallography is so unpredictable. Furthermore, claim 9 is drawn to a method claim which inadequately describes and enables the making of a crystal containing SEQ ID No: 3. To be more precise, for a

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method claim to adequately describe how to make a particular protein, the exact and specific crystallization conditions e.g. temperature, buffer, salt, protein concentration etc., is required.

19. The Examiner has joined claim 17 under the same scope of 35 U.S.C. 112 1<sup>st</sup> paragraph rejections recited for the crystals. This is because whether the limitation is explicitly stated or not in the claim, when one skilled in the art reads the claims, in light of the specification, it is clearly understood that the composition encompasses crystals of SEQ ID No: 3. As stated in the rejections of record, however, Applicants are not enabled nor do they have written description for anything other than the single crystal species that they have described. This is due to the arts enormous unpredictability in making even a single protein crystal. Thus, the claim that reads on a composition, despite the lack of recitation that is implicitly drawn to crystals, still does read upon all crystals of SEQ ID No: 3 and therefor the claim is rejected for including all possible species/crystal forms of SEQ ID No: 3. The rationale and basis for doing so can be explained by the recent En Banc Federal Circuit Court of Appeals decision of *Phillips v. AWH Corp.*, 75 USPQ2d 1321 (CA FC 2005) that clearly states that a patents meaning of various words in a claim must be interpreted by the *intrinsic* evidence provided and described in the specification and not on the extrinsic evidence provided by dictionaries or even the common every day general understanding of the terms. The case begins by the general analysis stating:



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"Intrinsic evidence is primary source for determining meaning of claim terms, since claims themselves provide substantial guidance as to meaning of particular terms, since claims are part of, and therefore must be read in view of, specification, which is always highly relevant to claim construction analysis, and is single best guide to meaning of disputed terms, and since prosecution history, like specification, was created by patentee in attempting to explain and obtain patent, and provides evidence of how U.S. Patent and Trademark Office and inventor understood patent, and thus can often inform meaning of claim language by demonstrating how inventor understood invention and whether inventor limited scope of invention in course of prosecution."

The Opinion written by Judge Bryson further reads:

"The claims, of course, do not stand alone. Rather, they are part of "a fully integrated written instrument," *Markman*, 52 F.3d at 978, consisting principally of a specification that concludes with the claims. For that reason, claims "must be read in view of the specification, of which they are a part." *Id.* at 979. As we stated in *Vitronics*, the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." 90 F.3d at 1582.

This court and its predecessors have long emphasized the importance of the specification in claim construction. In *Autogiro Co. of America v. United States*, 384 F.2d 391, 397-98 [155 USPQ 697] (Ct. Cl. 1967), the Court of Claims characterized the specification as "a concordance for the claims," based on the statutory requirement that the specification "describe the manner and process of making and using" the patented invention. The Court of Customs and Patent Appeals made a similar point. *See In re Fout*, 675 F.2d 297, 300 [213 USPQ 532] (CCPA 1982) ("Claims must always be read in light of the specification. Here, the specification makes plain what the appellants did and did not invent ....").

In the instant situation, there are only two instances where Applicants contemplate a composition that could comprise the amino acid sequence of SEQ ID No: 3. On p. 2, paragraph 009 of the specification, an embodiment is described wherein a composition is provided of a protein in crystalline form that has 55, 65, 75, 85, 95, 97 or 99% or greater identity with residues 572-976, 596-900, or 60-883 of SEQ ID No: 1. The second composition contemplated is that of an isolated protein that compromises or consists of one or more of the protein

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sequences of EPHA2 taught herein for crystallizing EPHA2. Thus, when a skilled artisan reads claim 17 in light of the specification, the claim clearly encompasses SEQ ID No: 3 is a crystalline form and in a soluble form. However, as stated *supra*, Applicants are not enabled nor do they have written description for all types of crystals of SEQ ID No: 3 for the reasons of record.

### ***Conclusion***

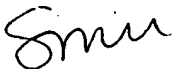
20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SMN

22 September 2006



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